AUTHORITY: 5 U.S.C. 504, 552, App. 2 605; 7 U.S.C. 138a, 2217; 15 U.S.C. 638, 1261–1282, 1451–1461, 3701–3711a; 21 U.S.C., 61–63, 141–149, 301–394, 467f, 679(b), 801–886, 1031–1309, 1401–1403; 35 U.S.C. 156; 42 U.S.C. 238, 241, 242, 242a, 242l, 242n, 242o, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1, 300ar–25–28, 300cc, 300ff, 1395y, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

SOURCE: 66 FR 30993, June 8, 2001, unless otherwise noted.

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

§5.10 Delegations from the Secretary of Health and Human Services to the Commissioner of Food and Drugs.

(a) The Secretary of Health and Human Services (the Secretary) has redelegated to the Commissioner of Food and Drugs (Commissioner), with authority to redelegate (except when specifically prohibited), all authority as follows:

(1) Functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), as amended, the Filled Milk Act (21 U.S.C. 61–63), the Federal Import Milk Act (21 U.S.C. 141 *et seq.*), the Federal Caustic Poison Act (44 Stat. 1406; see also Public Law 86–613, section 19, formerly section 18) and The Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), under section 12 of Reorganization Plan No. IV and Reorganization Plan No. 1 of 1953, including authority to administer oaths vested in the Secretary of Agriculture by 7 U.S.C. 2217.

(2) Functions vested in the Secretary under section 301 (Research and Investigations); section 307 (International Cooperation); and section 311 (Federal-State Cooperation) of the Public Health Service Act (the PHS Act) (42 U.S.C. 241, 2421, 243), as amended, which relate to the functions of the Food and Drug Administration.

(3) Functions vested in the Secretary under section 361 of the PHS Act (42 U.S.C. 264), as amended, which relate to the law enforcement functions of the Food and Drug Administration concerning the following products and activities: Biologicals (including blood and blood products); interstate travel sanitation (except interstate transportation of etiologic agents under 42 CFR part 72); food (including milk and food service sanitation and shellfish sanitation); and drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration.

(4) Functions vested in the Secretary under sections 351 and 352 of part F, subpart 1 of the PHS Act (42 U.S.C. 262 and 263), as amended (Biological Products), insofar as they relate to the functions assigned to the Food and Drug Administration.

(5) Functions vested in the Secretary under section 302(a) of the PHS Act (42 U.S.C. 242(a)), as amended, which relate to the determination and reporting requirements with respect to the medicinal and scientific requirements of the United States for controlled substances.

(6) Functions vested in the Secretary under section 303 of the PHS Act (42 U.S.C. 242a), as amended, which relate to the authorization of persons engaged in research on the use and effect of drugs to protect the identity of their research subjects with respect to drugs scheduled under Public Law 91–513 for which an investigational new drug application is filed with the Food and Drug Administration and with respect to all drugs not scheduled under Public Law 91–513.

(7) Functions vested in the Secretary pertaining to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1241) which relate to the determination of the safety and effectiveness of drugs or to approve new drugs to be used in the treatment of narcotic addicts.

(8) Functions vested in the Secretary pertaining to section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)), which relate to the merits of the research protocol and to the determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances listed in Schedule I of the Act.

(9) Functions vested in the Secretary pertaining to provisions of the Controlled Substances Act (21 U.S.C. 801 *et seq.*), which relate to administration of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(10) Functions vested in the Secretary under section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)), which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(11) Functions vested in the Secretary under section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)), which relate to the detention of any poultry carcass, part thereof, or poultry product.

(12) Functions vested in the Secretary under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

(13) Functions vested in the Secretary by amendments to the foregoing statutes subsequent to Reorganization Plan No. 1 of 1953.

(14) Function of issuing all regulations of the Food and Drug Administration, except as provided in § 5.11. The reservation of authority contained in Chapter 2–000 of the Department Organization Manual shall not apply.

(15) Functions vested in the Secretary under section 1103 of Executive Order 11490, as amended by Executive Order 11921, which relate to emergency health functions as they pertain to the operations and functional responsibilities assigned to the agency. This authority shall be exercised in accordance with section 102 and pertinent sections of part 30 of Executive Order 11490 and guidelines issued by the Federal Preparedness Agency of the General Services Administration and the Office of the Secretary.

(16) Function vested in the Secretary of authorizing and approving miscellaneous and emergency expenses of enforcement activities.

(17) Functions vested in the Secretary under the Federal Advisory Committee Act, Public Law 92–463, to:

(i) Renew, recharter, amend and terminate established Federal Advisory Committees;

(ii) Authority to approve waivers to appoint committee members to established Federal Advisory Committees;

(iii) Authority to close review meetings following approval by the Office of the General Counsel based on a determination that the Advisory Committee meeting or a portion thereof may be closed to the public under the provisions of 5 U.S.C. 552b(c) and section 10(d) of the Federal Advisory Committee Act. These authorities are to be exercised in accordance with the requirements of 5 U.S.C. 552b; the Federal Advisory Committee Act (Public Law 92–463); Departmental regulations (45 CFR part 11, superseded by 41 CFR part 101–6); and any other applicable statutes and regulations. These authorities may be redelegated.

(18) Functions vested in the Secretary under the second sentence of section 310(a) and under section 310(b) (Health Conferences and Health Education Information) of the PHS Act (42 U.S.C. 242o), as amended, to call for a conference and invite as many health authorities and officials of State or local public or private agencies or organizations as deemed necessary or proper on subjects related to the functions of the Food and Drug Administration, and to issue information related to health for the use of the public and other pertinent health information for the use of persons and institutions concerned with health services when such information is related to the functions of the Food and Drug Administration.

(19) Functions vested in the Secretary under section 2701 of the PHS Act (42 U.S.C. 238), as amended, to accept offers of gifts, excluding the acceptance of gifts of real property. Only the authority to accept unconditional gifts of personal property valued at $5,000 or less may be redelegated.

(20) Functions vested in the Secretary under section 362 of the PHS Act (42 U.S.C. 265), as amended, which relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health when such functions relate to the law enforcement functions of the Food and Drug Administration.

(21) Functions vested in the Secretary under section 401(a) of the Lead-Based Paint Poisoning Prevention Act, as amended by Public Law 94–317 (42 U.S.C. 4831(a)), relating to the prohibition of the application of lead-based paint to cooking, drinking, or eating utensils.

(22) Functions vested in the Secretary for the health information and health promotion program under title XVII of the PHS Act (42 U.S.C. 300u *et seq.*), as amended, insofar as the authorities pertain to functions assigned to the Food and Drug Administration. The delegation includes, but is not limited to, the authorities under: Section 1702(a)(1) and (3) and section 1704(1) and (2) (42 U.S.C. 300u–1(a) and (3) and 300u–3(1) and (2)). The delegation excludes the authority to select all Senior Executive Service, supergrade and equivalent, and Schedule C (GS–12 and above) positions; issue regulations; and submit reports to the President.

(23) To administer a Small Business Innovation Research Program under section 9 of the Small Business Act (15 U.S.C. 638), as amended. The delegation excludes the authority to issue regulations, establish advisory councils and committees, appoint members to advisory councils and committees, and submit reports to Congress.

(24) Functions vested in the Secretary under sections 982 and 983 of the Consumer-Patient Radiation Health and Safety Act of 1981 (the Act) (42 U.S.C. 10007 and 10008), as amended. The delegation excludes the authority to issue regulations and submit reports to Congress. The authority delegated under section 983 of the Act may only be exercised as it relates to functions assigned to the Food and Drug Administration.

(25) Functions vested in the Secretary under section 156 of title 35 of

the U.S. Code (35 U.S.C. 156), as amended, which allows for the extension of patent terms for human drug products, medical devices, food additives, and color additives subject to the Federal Food, Drug, and Cosmetic Act (the act). These authorities may be redelegated, except the authority to make due diligence determinations under section 156(d)(2)(B), which may not be redelegated to an Office below the Office of the Commissioner of Food and Drugs.

(26) Functions vested in the Secretary under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*) (the Act), as amended, and under Executive Order 12591 of April 10, 1987, as they pertain to the functions of the Food and Drug Administration. The delegation excludes the authority to issue regulations and submit reports to Congress; under section 11(a)(2) of the Act (15 U.S.C. 3710a(a)(2)) to approve agreements and contracts with invention management organizations; and under section 11(c)(3)(B) of the Act (15 U.S.C. 3710a(c)(3)(B)) to propose necessary statutory changes regarding conflict of interest.

(i) The authorities under sections 11(c)(5) (A) and (B) of the Act (15 U.S.C. 3710a (c)(5) (A) and (B)) to disapprove or require the modification of cooperative research and development agreements and licensing agreements after the agreement is presented to the Commissioner by the head of the laboratory concerned, and to transmit written explanation of such disapproval or modification to the head of the laboratory concerned, may be redelegated only to a senior official in the immediate Office of the Commissioner.

(ii) The following authorities may not be redelegated: The authority under section 11(b)(3)(D) of the Act (15 U.S.C. 3710a(b)(3)(D)) to waive a right of ownership which the Federal Government may have to an invention made under a cooperative research and development agreement; the authority under section 11(b)(3)(C) of the Act (15 U.S.C. 3710a(b)(3)(C)) to permit employees or former employees to participate in efforts to commercialize inventions they made while in the service of the United States; the authority under section 11(c)(3)(A) of the Act (15 U.S.C. 3710a(c)(3)(A)) to review employee standards of conduct for resolving potential conflicts of interest; the authority under section 13(a)(1) of the Act (15 U.S.C. 3710c(a)(1)) to retain any royalties or other income, except as provided in section 13(a)(2) of the Act (15 U.S.C. 3710c(a)2)); and the authority under section 13(a)(1)(A)(i) of the Act (15 U.S.C. 3710c(a)(1)(A)(i)) to pay royalties or other income the agency receives on account of an invention to the inventor if the inventor was an employee of the agency at the time the invention was made.

(iii) Any authorities under paragraph (a)(26) of this section delegated by the Commissioner may not be further redelegated.

(27) Functions vested in the Secretary under sections 4702, 4703, and 4704 of the Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1401–1403) that relate to pesticide monitoring and enforcement information, foreign pesticide information, and pesticide analytical methods. The delegation excludes the authority to submit reports to Congress.

(28) Functions vested in the Secretary under sections 2312(a)(1) and (2)(B), (b), and (c) (Use of Investigational New Drugs with Respect to Acquired Immunodeficiency Syndrome); 2314(c) (Scientific and Ethical Guidelines for Certain Treatments); and 2317(d) and (e) (Information Services) of title XXIII of the PHS Act (42 U.S.C. 300cc–12(a)(1) and (2)(B), (b) and (c), 300cc–14(c) and 300cc–17 (d) and (e)), as amended, insofar as these authorities pertain to the functions assigned to the Food and Drug Administration. The delegation excludes the authority to issue regulations, submit reports to the Congress, establish advisory committees or national commissions, and appoint members to such committees or commissions.

(29) Functions vested in the Secretary under section 2672(a)(1) (A) and (B) (Provisions Relating to Blood Banks) and section 2672(a)(2) (Information and Training Programs) of the PHS Act (42 U.S.C. 300ff–72(a)(1)(A) and (B) and (a)(2) *et seq.*), as amended, insofar as these authorities pertain to the functions assigned to the Food and Drug Administration. The delegations

exclude the authority to issue regulations, submit reports to the Congress, establish advisory committees or national commissioners, and appoint members to such committees or commissions.

(30) Functions vested in the Secretary under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter, which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of this section. The delegation excludes the authority to submit reports to Congress.

(31) Functions vested in the Secretary under part C, subtitle 2 of title XXI of the PHS Act (42 U.S.C. 300aa–25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1 note), as amended hereafter, as follows:

(i) Section 2125 of the PHS Act (42 U.S.C. 300aa–25)—Recording and reporting of information.

(ii) Section 2127 of the PHS Act (42 U.S.C. 300aa–27)—-Mandate for safer childhood vaccines.

(iii) Section 2128 of the PHS Act (42 U.S.C. 300aa–28)—Manufacturer recordkeeping and reporting.

(iv) Section 312 of the National Childhood Vaccine Injury Act of 1986—Related studies (42 U.S.C. 300aa–1 note).

(v) Section 313 of the National Childhood Vaccine Injury Act of 1986—Study of other vaccine risks (42 U.S.C. 300aa–1 note).

(vi) Section 314 of the National Childhood Vaccine Injury Act of 1986—Review of warnings, use instructions, and precautionary information (42 U.S.C. 300aa–1 note).

(vii) The delegation excludes the authority to issue regulations and submit reports to Congress.

(32) Functions vested in the Secretary under section 201(h)(4) of the Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended) (21 U.S.C. 811(h)(4)) to provide responses to the Drug Enforcement Administration's temporary scheduling notices. The delegation excludes the authority to submit reports to Congress.

(33) Functions vested in the Secretary under the Safe Medical Devices Act of 1990 (Pub. L. 101–629), as amended hereafter (e.g., 21 U.S.C. 360c note, 360i note, and 360j note). The delegation excludes the authority to submit reports to Congress.

(34) Functions vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Public Law 104–180), as amended hereafter. The delegation excludes the authority to issue reports to Congress.

(35) The Secretary has redelegated to the Commissioner of Food and Drugs, or his designee, the authority to take final action on matters pertaining to section 203 of the Equal Access to Justice Act (5 U.S.C. 504), and to develop procedures and regulations where necessary to supplement the Department's regulations, 45 CFR part 13.

(36) The Secretary has delegated to the Commissioner, the authority to administer and make decisions regarding the invention and patent program as they pertain to the functions of the Food and Drug Administration and to make determinations of rights in inventions and patents in which the Department has an interest. This delegation excludes the authority to submit reports to Congress and further, it excludes those authorities under the Stevenson-Wydler Technology Innovation Act of 1980, as amended by the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995, which are governed by a separate delegation (under §5.10(a)(26)). All authorities other than the authority under 35 U.S.C. section 203 (March-In Rights) may be redelegated.

(37) Functions vested in the Secretary under title III, Section 354, of the PHS Act (42 U.S.C. 262 *et seq.*), as amended. The authority pertains to the Food and Drug Administration's oversight of mammography facilities.

(38) The Deputy Assistant Secretary for Health Management Operations, Public Health Service, has redelegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority to certify true copies of any books, records, or other documents on file within the Food and Drug Administration, or extracts from such; to certify that true copies are true copies of the entire file of the Administration; to certify the complete original record or to certify the nonexistence of records on file within the Administration; and to cause the Seal of the Department to be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(39) The Secretary of Health and Human Services has redelegated to the Commissioner, of Food and Drugs, under 45 CFR 5b.8 regulations, appeal authority to take final action upon an individual's appeal of a refusal to correct or amend the individual's record when the appeal has been made by the individual under Privacy Act regulations (part 21 of this chapter and 45 CFR part 5b). The authority may not be redelegated.

(b) The Chief Counsel of the Food and Drug Administration has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, under section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335), section 4 of the Federal Import Milk Act (21 U.S.C. 144), and section 9(b) of the Federal Caustic Poison Act.

§ 5.11 Reservation of authority.

(a) Notwithstanding provisions of § 5.10 or any previous delegations of authority to the contrary, the Secretary of Health and Human Services (Secretary) reserves the authority to approve regulations of the Food and Drug Administration, except regulations to which sections 556 and 557 of title 5 U.S.C. apply, which:

(1) Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, or other subjects of regulation; or

(2) Present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices, or other subjects of regulation.

(b) Nothing in this section precludes the Secretary from approving a regulation, or being notified in advance of an action, to which sections 556 and 557 of title 5 U.S.C. apply, which meets one of the criteria in paragraph (a) of this section.

(c) This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and it is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the Food and Drug Administration, any agency, officer, or employee of the United States, or any person. Regulations issued by the Food and Drug Administration without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

Subpart B—General Redelegations of Authority

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

(a) Final authority of the Commissioner of Food and Drugs (Commissioner) is redelegated as set forth in these subparts. The Commissioner may continue to exercise all authority delegated in subparts B through L.

(b) The following officials are authorized to perform all of the functions of the Commissioner. These officials may not further redelegate this authority, or any part of this authority, except as elsewhere specified:

(1) Deputy Commissioner;

(2) Associate Commissioner for Regulatory Affairs;

(3) Senior Associate Commissioner;

(4) Senior Associate Commissioner for Management and Systems;

(5) Senior Associate Commissioner for Policy, Planning, and Legislation; and

(6) Deputy Commissioner for International and Constituent Relations.

(c)(1) During the absence or disability of the Commissioner or in the event of